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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,856	03/05/2001	Yat Sun Or	ENP019	5605

36078 7590 05/16/2003

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/800,856

Applicant(s)

OR ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 5-7 and 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicants' response filed 1 April 2003 (Paper No. 10) as to amendment of claims 1-4 has been entered. The following Office Action is applicable to the pending claims 1-4 and 8.

Please note that the rejection(s) not explicitly stated and/or restated below are withdrawn.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang, N. Y. *et al.* (US Pat. No. 5239037).

Wang *et al.* disclose a cyclosporin structure that meets the limitations of the Formula (I) structure of claim 1 of the instant application (see patent column 8, formula III wherein "W" is 1 carbon atom, "Y" is Oxygen atom, "m" = 0, and "Z" is OR_a [R_a = -CH₃]). Since Applicant elects "B" as - α -amino butyric acid, "U" as -(D) alanine, "X" as absent, and "Y" as COOCH₃ for patent examination, claims 2-4 are anticipated by the patent reference as well.

In addition, Wang *et al.* teach a carrier, e.g., bovine serum albumin (see claim 6, and column 4, lines 24-29), as applied to claim 8 of the current application.

Response to the rejection under 35 USC 102

The response filed 1 April 2003 asserts that because Formula III of Wang et al. reference contains an unsubstituted alkyl ester group, i.e., R_a group of Formula III refers to an unsubstituted alkyl group, the compound set forth in Formula III does not read upon claim 1 of the instant application (see page 13, the first paragraph). The applicants' argument is unpersuasive because Wang et al. compound shown in Formula III (column 8) does indicated that -OR_a encompasses -OCH₃ wherein R_a is a substituted group (note that nowhere in Wang et al. patent indicates that R_a is unsubstituted group in Formula III). Therefore, the rejection is maintained.

Also, the response asserts that because the specification defines the claimed pharmaceutical acceptable carrier as "a non-toxic, inert solid, semi-solid or liquid filler, diluent, encapsulating material or formulation auxiliary of any type", the carrier taught by Wang et al., e.g., bovine serum albumin does not applied to claims 1 and 8 of the instant application (see pages 13-14 of the response). The applicants' argument is not persuasive since, contrary to the applicants' assertion, the serum albumin is a pharmaceutical acceptable diluent or carrier which meets the definition of pharmaceutical carrier by the current disclosure. Thus, the rejection stated above maintained.

Provisional Rejection - Obviousness Type Double Patenting

Claims 1-4 and 8 of this application conflict with Claims 1-3 and 11 of Application No. 09976219. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may

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be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 8 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 11 of copending Application No. 09976219. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

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The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 1 of Application 09976219 [see formula I (A1)] discloses the same subject matter as that of claim 1 of the instant application with respect to the generic structure of a cyclosporin analog.

Claims 2 and 3 of Application 09976219 set forth the limitations for claim 1 from which claims 2 and 3 depend, which are obvious variation of claims 2 and 3 of the current application.

Claim 4 of Application 09976219 sets forth the compound wherein $Y = (\text{SO})\text{Ph}$ is an obvious structural variation of the compound wherein $Y = \text{C}(\text{O})\text{SCH}_2\text{Ph}$ of claim 4 of the current application.

Claim 11 Application 09976219 sets forth a pharmaceutical composition which is the same as that of claim 8 of the current application; though the scope of the claim is different, the subject matter of the claims of the reference application and the current application are the same, *i.e.*, the composition comprising a cyclosporin compound of claim 1 and a pharmaceutically acceptable carrier.

Therefore, the instant application and copending application claims are obvious variation.

Claims 1-4 and 8 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 11 of copending Application No. 09975923. This is a

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provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 1 of Application 09975923 [see formula I (A1)] discloses a cyclosporin variant that is an obvious structural variation of that set forth in the claim 1 [formula (1)] of the current application. In formula I of 09975923, moiety of "A" is an obvious structural variation over the moiety of "A" set forth in formula (1) of the present application in that, provided that "Y" is a functional group ("X" is absent), Application 09975923 discloses the same limitation for the moiety "Y" as that of the present application. Furthermore, because the specification of 09975923 does not set forth importance of type of chemical bond (the secondly adjacent to "X-Y" linkage) or/and related configuration thereof, the "Y" moieties in the both the reference application and the current application are regarded as the structural or functional variations each other.

Claims 2-4 of the Application 09975923 and claims 2-4 of the current application disclose the same subject matter.

Also, claim 9 of the Application 09975923 set forth the same subject matter with regard to a pharmaceutical composition as that of claim 8 of the current application, *i.e.*, the composition comprising a cyclosporin compound of claim 1 and a pharmaceutically acceptable carrier.

Therefore, the instant application and Application 09674266 claims are obvious variations, and they are not patentably distinct from each other.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

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SWL
Samuel Wei Liu, Ph.D.

May 12, 2003

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER